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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/073,464      | 02/11/2002  | James Tiedje         | MSU-06787           | 4392             |

7590 03/27/2006

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EXAMINER

BAUSCH, SARAE L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/073,464 | <b>Applicant(s)</b><br>TIEDJE ET AL. |  |
|                              | <b>Examiner</b><br>Sarae Bausch      | <b>Art Unit</b><br>1634              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Claims*

1. This action is in response to papers filed 12/23/2005. Currently, claims 1-6, 8-14 are pending in the instant application. Claim 7 and 15-21 have been canceled. Claims 1 and 9 has been amended. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

### *Withdrawn Rejections*

2. The rejections of claims 1-15, under 35 U.S.C. 112, first paragraph, made in section 3, page 3 of the previous office action, is withdrawn in view of the amendment to the claims.

3. The rejections of claims 1-15, under 35 U.S.C. 102(e), made in section 4, page 4 of the previous office action, is withdrawn in view of the amendment to the claims.

4. The rejections of claims 1-15, under 35 U.S.C. 102(e), made in section 4, page 4 of the previous office action, is withdrawn in view of the amendment to the claims

### *Maintained Rejections*

#### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1634

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5, 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuiper et al. (Current Opinion in Biotechnology, 1999, 10:511-516) and Greisen et al. (J.Clin. Microbial. 1994, vol. 32, pp 335-351). It is noted that this rejection was previously presented in section 6 of the previous office action mailed 07/01/2005 and has been maintained for reasons of record in the previous office action.

#### ***Response to Arguments***

7. The response asserts on page 7 of the response mailed 12/23/2005, that the Examiner has not taught every element of the claimed invention because neither Kuiper nor Greisen disclose hybridizing labeled fluorescent reference DNA from at least four strains of reference bacteria and hybridizing the fluorescently labeled target DNA wherein reference bacteria are members of the group consisting of said plurality of bacterial species arrayed on a solid support. This response has been thoroughly reviewed but not found persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicants arguments that Kuiper et al. nor Greisen disclose the claimed invention, Kuiper et al. teach spotting amplicons of open reading frames in the genome sequence of interest on a defined support material and teach that over 100,000 spots can be accommodated on glass slides providing sufficient combinatorial possibilities for bacterial genome application (see page 512, 2<sup>nd</sup> column, 1<sup>st</sup> full paragraph). Kuiper further

Art Unit: 1634

teaches differentially fluorescent-labeled wild type and mutant cDNA to allow for multiplexing. As stated in the rejection of record, Kuiper et al. does not teach the use of at least four strains of reference bacterial species, however Kuiper et al. in view of Greisen et al. does teach modifying the method of using differentially labeled cDNA probes on a microarray as taught by Kuiper to include 12 different probes of seven reference bacterial species, as taught by Greisen to test for at least seven bacterial species causing meningitis. Therefore, Kuiper et al. and Greisen et al. teach the claimed invention.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

8. Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuiper et al. (Current Opinion in Biotechnology, 1999, 10:511-516) and Greisen et al. (J.Clin. Microbial. 1994, vol. 32, pp 335-351) as applied to claims 1-5, 7-13, and 15 above, and further in view of Arfin et al.. (J. Biol. Chem. 2000, vol. 275, pp. 29672-29684). It is noted that this rejection was previously presented in section 7 of the previous office action mailed 07/01/2005 and has been maintained for reasons of record in the previous office action.

#### ***Response to Arguments***

9. The response asserts on page 8 of the response mailed 12/23/2005, that the Examiner has improperly combined the Kuiper and Greisen reference and the obviousness rejection of these claims is unsupported by the references and therefore improper. The response asserts that Arfin is not particularly relevant because it merely provides an example of methods that could be used by the Applicant and does not supplement the missing teaching of Kuiper and Greisen. This response has been thoroughly reviewed but not found persuasive. It is noted that applicant did

Art Unit: 1634

not provide, nor address in the previous sections of their response, arguments that support that the examiner improperly combined Kuiper and Greisen. In response to applicant's argument that Kuiper and Greisen were improperly combined, applicant does not explicitly address reasons why the references were improperly combined and therefore the argument will not be addressed. In response to applicants arguments that Arfin is not particularly relevant because it merely provides an example of methods that could be used by Applicant, it is noted that Kuiper and Greisen further in view of Arfin teach using statistical analysis of data generated from the microarray analysis of the identification of bacteria. Arfin teaches replication and appropriate statistical analysis for determining accuracy of DNA microarray measurements and one of ordinary skill in the art would have modified the teachings of Kuiper and Greisen to improve the analysis of identification of bacteria by including statistical analysis of the data to determine the accuracy of the DNA microarray measurements.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

### ***Conclusion***

10. No claims allowable over the art.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1634

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and

Application/Control Number: 10/073,464

Page 7

Art Unit: 1634

history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

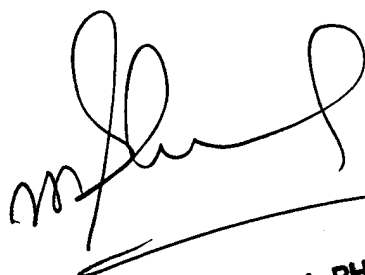
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Sarae Bausch, PhD.

Examiner

Art Unit 1634



**RAM R. SHUKLA, PH.D.**  
**SUPERVISORY PATENT EXAMINER**